

IN THE UNITED STATES PATENT
AND TRADEMARK OFFICE

In re Application of: Bainbridge *et al.*)
Serial No.: To be assigned) Examiner: To be assigned
Filed: December 4, 2000) Group Art Unit: To be assigned
For: EXTRACORPOREAL BLOOD)
 PROCESSING METHODS AND)
 APPARATUS)

Commissioner for Patents
Box Patent Application
Washington, DC 20231

CERTIFICATE OF EXPRESS MAIL	
I, <u>Jeannie Woods</u> , do hereby certify that the foregoing documents are being deposited with the United States Postal Service as Express Mail, postage prepaid, in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231, on this date of <u>12/4/00</u> .	
Name	<u>Jeannie Woods</u>
Express Mail Label Number	<u>EKT42455815US</u>
Date of Deposit	<u>12/4/00</u>

PRELIMINARY AMENDMENT

Dear Sir:

Please amend the above-identified patent application filed herewith as follows.

In the Specification:

Page 1, after the title, but before the first sentence, please enter the following:

-- This patent document is a continuation claiming the benefit of the U.S. Patent Application, Serial Number 08/924,519; filed on September 5, 1997. --

In the Claims:

1. (Amended) A method for extracorporeal collection of blood components from a donor/patient, comprising:

flowing blood into a blood processing vessel for continuous blood processing;

separating platelets from said blood within said blood processing vessel;

[collecting at least a portion of said platelets in a platelet collection reservoir separate from said blood processing vessel;]

separating red blood cells from said blood within said blood processing vessel continuously with said step of separating platelets;

collecting at least a portion of said separated red blood cells in a red blood cell collection reservoir separate from said blood processing vessel, wherein said platelet separation [and collection] step[s are] is completed [separate from] continuously with said red blood cell separation and collection steps.

2. (Amended) A method as recited in Claim 1, wherein said method [platelet separation and collection steps are] is completed prior to said red blood cell separation and collection steps further comprises establishing an AC ratio of between about 6 and 16.

3. (Amended) A method as recited in Claim 1, wherein prior to said red blood cell [separation and] collection step[s, and separate from said platelet separation and collection steps] , said method further comprises a red blood cell collection set-up phase including:

[separating red blood cells from said blood within said blood processing vessel;]

establishing [an AC ratio in the blood processing vessel of between about 6 and 16 and] a packing factor of at least about 11 within separated red blood cells within said blood processing vessel.

4. (Amended) A method as recited in Claim 3, wherein said packing factor is established to be about 13 [, and wherein said AC ratio is established to be about 8] .

5. (Amended) A method as recited in Claim 3, wherein an AC ratio is established to be between about 6 and 16 [said set-up phase further including:

flowing blood components out of said blood processing vessel, wherein substantially all of said blood components flowing out of the blood processing vessel are accumulated for infusion to a donor/patient] .

6. (Amended) A method as recited in Claim 3, wherein an AC ratio is established to be about 8 [further comprising:

removing said blood from a donor/patient through a single needle;

returning uncollected components of said blood to said donor/patient through said single needle] .

7. (Amended) A method as recited in Claim 1 [6] , said set-up phase further including:

flowing separated blood components out of said blood processing vessel, wherein substantially all of said separated blood components flowing out of the blood processing vessel are accumulated for infusion to a donor/patient for at least a first volume of said blood processing vessel [wherein said removing and returning steps are alternately and repeatedly performed during corresponding blood processing and blood component return modes, respectively] .

8. (Amended) A method as recited in Claim 7 [6], wherein [during said platelet separation and collection steps], said set-up phase of said method further comprises:

[recirculating a portion of said uncollected blood components into said blood processing vessel; and,

wherein during said red blood cell separation and collection steps, said method includes:]

returning substantially all of said [uncollected] separated blood components to said donor/patient for at least two volumes of said blood processing vessel.

9. (Amended) A method as recited in Claim 3, wherein said blood is flowed into said blood processing vessel at a flow rate, and said establishing step of said set-up phase comprises:

reducing said flow rate.

10. (Amended) A method as recited in Claim 3, wherein said blood processing vessel is rotated at an rpm rate, and wherein said establishing step of said set-up phase comprises:

increasing said rpm rate.

11. (Amended) A method as recited in Claim 3, said establishing step of said set-up phase further comprises [including] :

maintaining a predetermined anticoagulant infusion rate to said donor/patient.

12. (Amended) A method as recited in Claim 3, said establishing step of said set-up phase further comprises [including] :

continuously removing platelets [and plasma together] through a [common] platelet port from said blood processing vessel.

13. (Amended) A method as recited in Claim 1, wherein during said platelet separation [and collection] step[s] and during said RBC separation and collection steps said method further comprises:

continuously separating plasma from said blood within said blood processing vessel;
[collecting] continuously removing at least a portion of said separated plasma [in]
through a plasma port from said blood processing vessel [collection reservoir] .

14. (Amended) A method as recited in Claim 1, wherein during said platelet separation step and said red blood cell separation and collection steps , said method further comprises:

establishing a blood component interface between separating blood components within said blood processing vessel, said interface including a red blood cell component disposed in a radially outwardmost disposition, a buffy coat component including a platelet component adjacent said red blood cell component, and a plasma component disposed in a radially inwardmost disposition adjacent said buffy coat component

[separating plasma from said blood within said blood processing vessel;
collecting at least a portion of said separated plasma in a plasma collection reservoir] .

15. (Amended) A method as recited in Claim 14 [1] , wherein said blood processing vessel further comprises [ing]:

a red blood cell outlet port for continuously removing said red blood cell component from said blood processing vessel

[adding a storage solution to said red blood cells collected in said red blood cell collection reservoir] .

16. (Amended) A method as recited in Claim 15, wherein said blood processing vessel further comprises a platelet outlet port for continuously removing said platelet component from said blood processing vessel [storage solution is added through an assembly having a sterile barrier filter] .

17. (Amended) A method as recited in Claim 16 [1], wherein said blood processing vessel further comprises [ing] :

a plasma outlet port for continuously removing said plasma component from said blood processing vessel [leukoreduction filtering of said red blood cells collected in said red blood cell collection reservoir].

18. (Amended) A method for extracorporeal collection of blood components from a donor/patient comprising:

removing blood from a donor/patient through a single needle;

continuously flowing said blood into a blood processing vessel;

continuously separating platelets from said blood within said blood processing vessel;

[collecting] continuously flowing at least a portion of said platelets [in] out of said blood processing vessel through a platelet [collection] outlet line [reservoir separate from said blood processing vessel];

continuously separating red blood cells from said blood within said blood processing vessel;

[collecting] continuously flowing at least a portion of said separated red blood cells out of said blood processing vessel through [in] a red blood cell outlet line [collection reservoir separate from said blood processing vessel,] wherein said platelet separation and [collection] flowing steps are completed [separate from] simultaneously with said red blood cell separation and [collection] flowing steps;

collecting red blood cells in a red blood cell collection reservoir [returning uncollected blood components of said blood to said donor/patient through said single needle] .

19. (Amended) A method as recited in Claim 18, further comprising:

continuously separating plasma from said blood within said blood processing vessel;

[collecting] continuously flowing at least a portion of said plasma [in] out of said blood processing vessel through a plasma outlet line [collection reservoir separate from said blood processing vessel], wherein said plasma separation and [collection] flowing steps are completed at least partially contemporaneous with said platelet separation and [collection] flowing steps.

20. (Amended) A method as recited in Claim 18, wherein prior to said red blood cell [separation and] collection step [s, and separate from said platelet separation and collection steps], said method further comprises a red blood cell collection set-up phase including:

[separating red blood cells from said blood within said blood processing vessel;]
establishing a hematocrit of at least about 75% within said separated red blood cells within said blood processing vessel and an AC ratio within said blood at about 8.

21. (Amended) A method as recited in Claim 20, said method further comprising:
maintaining said hematocrit and AC ratio during said red blood cell separation, flowing
and collection steps.

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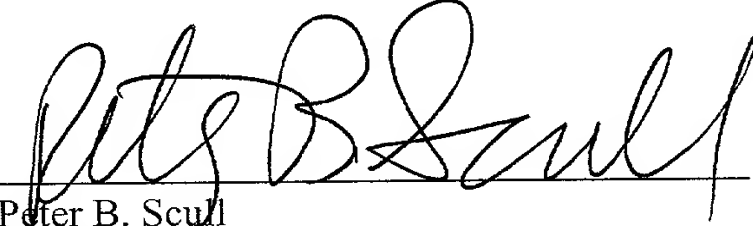
REMARKS

Applicants respectfully submit this Preliminary Amendment presenting amendments to all twenty-one claims which shall then be pending in this continuation application. Entry of these amendments prior to examination and calculation of the filing fee is thus respectfully requested.

If prosecution can be expedited in any fashion by telephonic conference, the Examiner is thus urged to call the undersigned representative at the below-printed telephone number.

Respectfully submitted,

December 4, 2000
Date


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